

IN THE SPECIFICATION

Page 4, line 1, amend the line as follows:

~~DETAILED DESCRIPTION OF THE INVENTION~~

Page 8, rewrite the section of the specification that begins on line 7 as follows:

--A non-limiting example of the unit formulation for the formation of the nucleus is:

granulate (from above)	68mg
hydroxypropylmethylcellulose	31mg
lactose	75mg
aerosil 200	0.35mg
Mg stearate	1.65mg--

5) Formation of delayed release nucleus: controlled pressure compression in a tablet press to obtain nucleus hardness equal to 7-8kN.

6) Preparation of the melatonin solution for the "cortex" of the tablets, containing the following excipients: hydroxypropylmethylcellulose, lactose, ethyl alcohol, purified water.

A nonrestrictive example of the formulation in solution for the "cortex" is:

melatonin	2.7%
hydroxypropylmethylcellulose	8.8%
lactose	6.4%
titanium dioxide	0.8%
ethyl alcohol	17.3%
purified water	64%--

Page, 16, line 1 rewrite the entire page as follows:

- a) only natural compounds are used which are allowed in human nutrition, in opposition to chemical compounds of synthetic origins used in the retard forms or existing time release formulations;
- b) the formulation is simple and inexpensive;
- c) the formulation consists of a single, small tablet (6mm. in diameter) and this increases the compliance;
- d) the quali-quantitative formulation can be reproduced at industrial level (two batches were produced independently of the pilot batches);
- e) the formula is very effective and allows the release of the active ingredients in the predicted time.

The formulations according to this invention may also be used for the preparation of functional foods, or herbal products, or nutritional supplements, that is, preparations that within a complex dietary management program may integrate the diet in individuals having intra- and extracellular deficiencies of melatonin and therefore with altered metabolic processes. According to this invention the formulations can also contain vitamins, minerals, aminoacids, fatty acids, antioxidants, vegetable extracts, animal extracts, or other nutrients or foods as active ingredients, which, within a complex dietary management program may integrate the diet in individuals having intra- and extracellular deficiencies of melatonin and therefore with altered metabolic processes.

~~CLAIMS-~~

- ~~1. Controlled release formulations containing melatonin, characterized by being made from an interior slow release nucleus and from an exterior fast release "cortex", both containing melatonin in equal or different doses.~~
- ~~2. Formulations according to claim 1, characterized by the fact that the melatonin content may be between 0.1 and 100mg either in the interior nucleus or in the exterior "cortex".~~
- ~~3. Formulations according to claim 2, characterized by the~~

~~fact that the fast release "cortex" contains the active ingredient preferably in a quantity of 1mg and the slow release nucleus contains the main ingredient preferably in a quantity between 0.5 and 3mg (inclusive).~~

~~4. Process for the preparation of controlled release formulations characterized by the fact that an interior nucleus and an exterior "cortex" must be prepared, both containing an--~~